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List of abbreviations

COC	Combined oral contraceptive
CIC	Combined injectable contraceptive
DMPA	Depot medroxyprogesterone acetate
ECP	Emergency contraceptive pill
HIV	Human immunodeficiency virus
IPPF	International Planned Parenthood Federation
IUD	Intrauterine device
NET-EN	Norethisterone enantate
NSAID	Non-steroidal anti-inflammatory drug
PID	Pelvic inflammatory disease
POI	Progestogen-only injectable
POP	Progestogen-only pill
STI	Sexually transmitted infection
WHO	World Health Organization

Executive summary

This document is one of two evidence-based cornerstones of the World Health Organization's (WHO) new initiative to develop and implement evidence-based guidelines for family planning. The first cornerstone, Improving Access to Quality Care in Family Planning. Medical Eligibility Criteria for Contraceptive Use (second edition) published in 2000, provides guidance for who can use contraceptive methods safely. This document, the Selected Practice Recommendations for Contraceptive Use, provides guidance for how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate. The recommendations contained in this document are the product of a process that culminated in a scientific Working Group meeting convened by WHO and held in London, 3–6 October 2001. The meeting brought together 33 participants from 16 countries to make selected practice recommendations for contraceptive use. The recommendations were the Working Group's response to 23 specific questions selected by WHO, based on 1) important controversies or inconsistencies in existing guidance, 2) the likelihood that relevant evidence was available, and 3) proposals from Working Group participants and family planning organizations/agencies.

The document provides selected practice recommendations based on the best available evidence and is intended to be used by policy-makers, programme managers, and the scientific community. It aims to provide guidance to national family planning/reproductive health programmes in the preparation of guidelines for service delivery of contraceptives. At appropriate intervals, WHO will update and add to the selected practice recommendations in this document.

These recommendations are available on the WHO web site (www.who.int/reproductive-health). The web site will also provide additional information determined by WHO to be relevant to these practice recommendations, pending the next formal consensus Working Group meeting. WHO encourages research to address the key unresolved issues noted in this document.

Overview

In 1999, WHO reviewed its family planning guidance and determined that the creation of new evidence-based guidelines was warranted. Accordingly, the World Health Organization through its Department of Reproductive Health and Research initiated the creation of a new series of evidence-based family planning guidelines beginning with the second edition of Improving Access to Quality Care in Family Planning. Medical Eligibility Criteria for Contraceptive Use, published in 2000. The two evidence-based cornerstones of this series (Figure 1) are the Medical Eligibility Criteria, which provides guidance regarding who can use contraceptive methods safely, and this document, the Selected Practice Recommendations for Contraceptive Use, which provides guidance regarding how to use contraceptive methods safely and effectively. These two documents give evidence-based guidance for choosing (the Medical Eligibility Criteria) and for using (the Selected Practice Recommendations) contraceptive methods. The forthcoming third and fourth documents, the Decision-Making Tool for Family Planning Clients and Providers

and the Handbook for Family Planning Providers, are intended to improve the quality of the family planning encounter and will be derived from the Medical Eligibility Criteria and the Selected Practice Recommendations. These four documents comprise the four cornerstones of WHO's family planning guidance. This guidance is best interpreted and used in a broader context of reproductive and sexual health care.

Reproductive and sexual health care

> "Reproductive rights embrace certain human rights that are already recognised in national laws, international human rights documents and other relevant consensus documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number and spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health." (para. 95, Beijing Platform for Action, 1995)

Reproductive and sexual health care including family planning services and information is recognized not only as a key intervention for improving the health of women, men and children but also as a human right. All individuals have the right to access, choice, and the benefits of scientific progress in the selection of family planning methods. A rights-based approach to the provision of contraceptives assumes a holistic view of clients, which includes taking into account clients' sexual and reproductive health care needs and considering all appropriate eligibility criteria and practice recommendations in helping clients choose and use a family planning method.

Over the past 30 years, there have been significant advances in the development of new contraceptive technologies, including transitions from high-dose to low-dose estrogen combined oral contraceptives (COCs) and from inert to copper and levonorgestrel-releasing intrauterine devices (IUDs). In addition, progestogen-only injectables (POIs), combined injectable contraceptives (CICs), and progestogen-only implants have been introduced. Advances in scientific knowledge and in research and development in recent decades have resulted not only in an increasingly wider choice of new contraceptive methods, but also in improvements in the safety and effectiveness of existing methods. However, the full range of modern family planning methods still remains unavailable to at least 350 million couples worldwide, many of whom wish to space or prevent another pregnancy. Even when family planning methods are accessible and individuals wish to space or limit births, family planning services are often under-used.

Many factors contribute to the gap between access to, and use of, services. In addition to many logistic, social and behavioural obstacles to meeting the contraceptive needs and wishes of individuals and couples, there may be obstacles that stem from the structure, organization or procedures of the health system that can be corrected. To meet people's needs and close the existing large gap in quality services, reproductive health care providers, programmes and contraceptive suppliers will need to improve services, and information will need to be disseminated about new contraceptive developments, appropriateness of methods and introduction strategies.

Thus, WHO is giving priority to improving access to high-quality care in family planning through a variety of strategies. These include: ensuring that women's and men's rights and perspectives are taken into account in the planning, management and evaluation of services; promoting the widest availability of different contraceptive methods so that people may select what is most appropriate to their needs and circumstances; ensuring that contraceptive counselling and service delivery will be based on eligibility criteria and practice recommendations that are supported by a scientific rationale; and conducting research to develop new family planning methods and improve existing ones.

Delivery of care in accordance with the client's human and reproductive rights is fundamental to quality of care. The development of international norms for eligibility criteria and practice recommendations for contraceptive use is only one aspect of improving the quality of reproductive health care. Many family planning programmes have included screening, treatment and follow-up procedures that reflect high standards of public health and clinical practice but should not be seen as eligibility or use requirements for specific contraceptive methods. These procedures include the screening and treatment of cervical cancer, anaemia and sexually transmitted infections (STIs), and the promotion of breastfeeding and cessation of smoking. Such procedures should be strongly encouraged if the human and material resources are available to carry them out, but they should not be seen as prerequisites for the acceptance and use of family planning methods when they are not necessary to establish eligibility for the use or continuation of a particular method.

The selected practice recommendations for contraceptive use

This document addresses ongoing controversies and inconsistencies regarding how to maximize the effectiveness of contraceptive methods and how to manage their side-effects. For instance, current recommendations are inconsistent as to when in the menstrual cycle a method can be initiated, how consistent and correct use can be maintained, and how menstrual abnormalities that frequently lead to discontinuation can be addressed. The methods for which the existing guidelines have been most inconsistent include combined estrogen-progestogen and progestogen-only oral contraceptives, injectable and implantable hormonal contraceptives; IUDs; fertility awareness-based methods and emergency contraceptive pills. As Table 1 shows, the effectiveness of some of these methods varies substantially depending on whether they are used consistently and correctly. The gap between the effectiveness of perfect and typical use is at least partially explained by inconsistent or unclear guidance about how to use these methods properly. The willingness and ability of contraceptive users to use their methods effectively also depends on minimizing and managing side-effects.

Like the Medical Eligibility Criteria, these Selected Practice Recommendations are meant to provide guidance that is both evidence-based and consensus-based. They will be reviewed and updated in a timely manner and are meant to be used by policy-makers, family planning programme managers and the scientific community. They are to be used as a reference and resource for the development of practice guidelines in the light of national health policies, needs, priorities and resources. Country situations and programme environments vary too greatly to set international guidelines for contraceptive use that apply in all settings and circumstances. Adaptations are best made by those well-acquainted with the health, habits and culture of the region, addressing questions or misperceptions held by providers as well as the needs and perspectives of women and men seeking contraception.

Table 1. Effectiveness of family planning methods[†]

Effectiveness group	Family planning method	Pregnancies per 100 women in first 12 months of use: As commonly used	Pregnancies per 100 women in first 12 months of use: Used correctly & consistently
Always very effective.	Norplant implants	0.1	0.1
	Vasectomy	0.2	0.1
	Combined injectables[‡]	0.3	0.3
	DMPA and NET-EN injectables	0.3	0.3
	Female sterilization	0.5	0.5
	TCu-380A IUD	0.8	0.6
	Progestogen-only oral contraceptives (during breastfeeding)	1	0.5
Effective as commonly used. Very effective when used correctly and consistently.	Lactational amenorrhoea method	2	0.5
	Combined oral contraceptives	6–8	0.1
	Progestogen-only oral contraceptives (not during breastfeeding)	[§]	0.5[§§]
Only somewhat effective as commonly used. Effective when used correctly and consistently	Male condoms	14	3
	Coitus interruptus[§§]	19	4
	Diaphragm with spermicide	20	6
	Fertility awareness-based methods	20	1–9
	Female condoms	21	5
	Spermicides	26	6
	Cap		
	Nulliparous women	20	9
	Parous women	40	26
	No method	85	85

Key: 0–1 Very effective | 2–9 Effective | 10–30 Somewhat effective

Notes:

† Adapted from Hatcher RA, Rinehart W, Blackburn R, Geller JS and Shelton JD. The essentials of contraceptive technology. Baltimore, Johns Hopkins University Bloomberg School of Public Health, Population Information Program, 1997.

‡ UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. Facts about once-a-month injectable contraceptives: Memorandum from a meeting. Bulletin of the World Health Organization 1993; 70(6):677-689.

§ Outside the context of breastfeeding, progestogen-only contraceptives are somewhat less effective than combined oral contraceptives. See Hatcher RA, Trussell J, Stewart F, Cates Jr W, Stewart GK, Guest F, Kowal D. Contraceptive technology (17th edition). New York, Ardent Media Inc., 1998.

§§ Hatcher RA, Trussell J, Stewart F, Cates Jr W, Stewart GK, Guest F, Kowal D. Contraceptive technology (17th edition). New York, Ardent Media Inc., 1998.

Table 2. List of questions posed to the Working Group

1. When can a woman start combined oral contraceptives?
2. What can a woman do if she misses combined oral contraceptives?
3. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives or progestogen-only pills?
4. When can a woman start combined injectable contraceptives?
5. When can a woman have repeat combined injectable contraceptive injections?
6. When can a woman start progestogen-only pills?
7. What can a woman do if she misses progestogen-only pills?
8. What can a woman do if she vomits after taking emergency contraceptive pills?
9. When can a woman start progestogen-only injectables – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
10. When can a woman have repeat progestogen-only injectables – DMPA or NET-EN?
11. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable – DMPA or NET-EN?
12. When can a woman start using an implant?
13. What can be done if a woman experiences menstrual abnormalities using implants?
14. When can a copper-bearing IUD be inserted?
15. What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?
16. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?
17. What should be done if a woman using a copper-bearing IUD is found to be pregnant?
18. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?
19. What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?
20. What examinations or tests should be done routinely before providing a method of contraception?
21. How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?
22. What follow-up is appropriate for combined oral contraceptive, progestogen-only pill, implant and IUD users?
23. How can a provider be reasonably sure that a woman is not pregnant?

Method of work

This document is the product of a process that culminated in a scientific Working Group meeting convened by WHO and held in London, 3–6 October 2001, with the support of the International Planned Parenthood Federation (IPPF) to facilitate the participation of IPPF's International Medical Advisory Panel. The meeting brought together 33 participants from 16 countries to make selected practice recommendations for contraceptive use. (The list of participants is given as an annex to this document.) The recommendations were the Working Group's response to 23 specific questions selected by WHO, based on 1) important controversies or inconsistencies in existing guidance, 2) the likelihood that relevant evidence was available, and 3) proposals from Working Group participants and family planning organizations/agencies. The list of questions that were posed to the group is given in Table 2.

The Working Group was charged with reviewing evidence obtained primarily from a systematic review of the literature published from 1980 to 2000. The purpose of the review was to identify evidence to address the biomedical and behavioural components of the common clinical challenges represented by Questions 1–19. Questions 20–23 represented broader programmatic issues and were not addressed by the systematic review.

The systematic review began with a search of MEDLINE and POPLINE to identify studies that could potentially provide relevant evidence. Additional reports were identified from the reference lists in the articles obtained by the literature search. Each article was reviewed by WHO to determine its relevance to the questions posed, the quality of the evidence provided, and whether the evidence was directly or indirectly applicable to answering the questions (Table 3). This information, along with a detailed summary of the relevant evidence for each question, was provided to the Working Group as a background document prior to the meeting. In addition, individual members of the Working Group were asked to serve as resource persons for specific questions and were provided prior to the meeting with complete copies of all relevant reports reviewed in the background paper.

Four sub-groups met for the first two days of the meeting to draft preliminary recommendations for the 23 questions. The sub-groups were asked to make recommendations based on the evidence provided from the systematic review and on other relevant biomedical, behavioural, or programmatic evidence or considerations provided by sub-group members. Each sub-group was encouraged to base its recommendations on the best available evidence, to cite the level and applicability of the evidence, and to comment on the rationales for the recommendations made. In addition, the sub-groups were asked to determine major gaps in evidence and thereby identify key unresolved issues that would benefit from further research.

The sub-groups presented their recommendations and rationales to the plenary session convened on the final two days of the meeting. The entire Working Group then deliberated to reach consensus on final recommendations. After the meeting, the comments provided by the sub-group and plenary sessions deliberations were used by WHO to create the comments for each question in this document.

Table 3. Levels of evidence*

The levels and categories of evidence on which the recommendations were based were as follows:

Level 1: Evidence obtained from at least one properly designed randomized controlled trial.

Level II-1: Evidence obtained from well-designed controlled trials without randomization.

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

* U.S. Preventive Services Task Force. Guide to clinical preventive services, 2nd ed. Alexandria, Virginia: International Medical Publishing, 1996:862.

Types of evidence

Direct: The evidence was based on data directly addressing the question.

Indirect: The evidence was extrapolated from other relevant data.

How to use this document

This document is intended for adaptation at country and programme levels to reflect the diversity of situations and settings in which contraceptives are provided.

The document is organized by questions. For each question, the Working Group's recommendations are provided for key specific situations, along with the comments and key unresolved issues. Further, for questions addressed by the systematic review (Questions 1–19), the following information is also provided: 1) the phrasing of the question from which the literature search terms were derived, 2) the level of evidence and whether that evidence was directly or indirectly related to the question, and 3) the references identified by the systematic review and provided to the Working Group.

Issues of service quality and access that affect method use

While this document chiefly addresses selected practice recommendations for contraceptive use, there are many other considerations in the appropriate provision of contraceptive methods. WHO will be examining, in depth, these programmatic and service delivery concerns, in various programme settings, during the next phase of this initiative. However, it is critical, even at this stage, to bear in mind the following service delivery criteria, which are universally relevant to the initiation and follow-up of all contraceptive method use.

a) Clients should be given adequate information in order to make an informed, voluntary choice of a contraceptive method. Information given to clients to help them make this choice should at least include: understanding of the relative effectiveness of the method; correct use of the method; how it works; common side-effects; health risks and benefits of the method; signs and symptoms that would necessitate a return to the clinic; information on return to fertility after discontinuing method use; and information on STI protection.

b) For those methods that require surgical approaches, insertion, fitting and/or removal by a trained health care provider (sterilization, implants, IUDs, diaphragms, cervical caps), appropriately trained personnel in adequately equipped facilities must be available in order for those methods to be offered, and appropriate infection prevention procedures must be followed.

c) Adequate and appropriate equipment and supplies need to be maintained and held in stock (for example, contraceptive commodities, equipment and supplies for infection prevention procedures).

d) Service providers should be provided with guidelines (or client cards or other screening tools) to enable them to appropriately screen clients for conditions in which use of certain contraceptive methods would carry unacceptable health risks.

e) Service providers must be trained in providing family planning counselling to help clients make informed and voluntary decisions about their fertility. Counselling is a key element in quality of care and is also an important part of both initiation and follow-up visits and should respond to clients' needs, not only in contraception but also in relation to sexuality and the prevention of STIs, including infection with the human immunodeficiency virus (HIV).

Special considerations

Return to fertility

The use of contraceptive methods, with the exception of male and female sterilization, does not result in an irreversible change in fertility. Return to fertility is immediate with all methods, with the exception of DMPA and NET-EN; the median delay in return to fertility with these methods is 10 and 6 months, respectively, from the date of the last injection, regardless of the duration of their use. Male and female sterilization should be regarded as permanent methods.

STIs and contraception: dual protection

While the development of international norms for contraceptive provision is essential for quality of care in services, the social and cultural context of each client must also be considered. In this regard, the problems of exposure to STIs, including HIV, deserve special consideration because of the importance of both preventing pregnancy and preventing transmission of infection. When a risk of STI/HIV transmission exists, it is important that health care providers strongly recommend dual protection, either through the simultaneous use of condoms with other methods or through the consistent and correct use of condoms alone for both pregnancy prevention and disease prevention. Women and men seeking contraceptive advice must always be reminded of the importance of condom use for preventing the transmission of STI/HIV. Male latex condoms are proven to protect against STI/HIV when used consistently and correctly.

Adolescents

In general, adolescents are eligible to use any method of contraception and must have access to a variety of contraceptive choices. Age alone does not constitute a medical reason for denying any method to adolescents, although sterilization is rarely appropriate for this age group. While some concerns have been expressed regarding the use of certain contraceptive methods in adolescents (e.g., the use of progestogen-only injectables by those below 18 years), these concerns must be balanced against the advantages of avoiding pregnancy. It is clear that many of the same issues regarding appropriate contraceptive use that apply to older clients apply to young people. Social and behavioural issues are important considerations in the choice and use of contraceptive methods by adolescents. For example, in some settings, adolescents are also at increased risk for STIs, including HIV. While adolescents may choose to use any one of the contraceptive methods available in their communities, in some cases, using methods that do not require a daily regimen may be more appropriate. Adolescents, married or unmarried, have also been shown to be less tolerant of side-effects and therefore have high discontinuation rates. Method choice and use may also be influenced by factors such as sporadic patterns of intercourse and the need to conceal sexual activity and contraceptive use. For instance, sexually active adolescents who are unmarried have very different needs from those who are married and want to postpone, space or limit pregnancy. Expanding the number of method choices offered can lead to improved satisfaction, increased acceptance and increased prevalence of contraceptive use. Proper education and counselling both before and at the time of method selection can help adolescents address their specific problems and make informed and voluntary decisions.

Clients with special needs

Contraceptive provision to people with special needs requires additional consideration. Individuals with a physical disability represent such a group. Decisions on appropriate contraception must take into account the nature of the disability, the expressed desires of the individual and the nature of the method. Decisions must be based on informed choice. Similar considerations should be given to individuals with mental disability or with serious psychiatric disease. Where the nature of the condition does not allow for informed choice, contraceptives should be provided only after full discussion with all parties including guardians or care-givers. The reproductive rights of the individual must be considered in any such decisions. Selected practice recommendations may need to be modified for clients with special needs; for example, clients with mental disabilities may have difficulty

remembering to take pills daily. Clients with physical disabilities may have difficulty obtaining supplies or otherwise accessing the family planning services.

Programmatic implications

The goal of this document is to provide policy- and decision-makers and the scientific community with a set of recommendations that can be used for developing or revising national guidelines on selective practice recommendations for contraceptive use.

The document does not provide rigid guidelines but rather gives recommendations that provide a basis for the appropriate use of various contraceptives in view of the most up-to-date information available.

Because country situations and programme environments vary so greatly, it is inappropriate to set firm international guidelines on criteria for contraceptive use. However, it is expected that national programmes will use these recommendations as a reference tool, adapting them to develop their own contraceptive guidelines in the light of their national health policies, needs, priorities and resources. The intent is to help improve access to, and quality of, family planning services. These improvements must be made within the context of users' informed choice and medical safety. Adaptation is not always an easy task and is best done by those well-acquainted with the prevailing health situation, habits and culture.

Programmatic issues that need to be addressed include:

- informed choice,
- elements of quality of care,
- essential screening procedures for administering the methods,
- provider training and skills,
- referral and follow-up for contraceptive use as appropriate.

In the application of the selected practice recommendations to programmes, service delivery practices that are essential for the appropriate use of the contraceptive should be distinguished from practices that may be appropriate for good health care but are not related to use of the method. The promotion of good health care practices unrelated to safe and appropriate contraceptive use should be considered neither as a prerequisite nor as an obstacle to the provision of a contraceptive method, but rather as complementary to it.

As a next step, the selected practice recommendations in this document need to be adapted so as to be applicable to providers at all levels of the service delivery system. Countries will need to determine how far and by what means it may be possible to extend their services to the more peripheral levels. This may involve upgrading both staff and facilities where feasible and affordable, or may require the extension of the skills of certain categories of health personnel or a modest addition of equipment and supplies, and redeployment of space. It will also be necessary to address questions of misperceptions sometimes held by providers and users on the risks and side-effects of the methods and

to look closely at the needs and perspectives of women and men in the context of informed choice.

Summary and conclusions

The development and use of evidence-based and consensus-driven recommendations for contraceptive use will contribute to improvements in the quality of family planning services. Such recommendations increase the competence and confidence of service providers as they assist their clients in choosing and using contraceptive methods. This in turn should contribute to increased satisfaction and confidence among those clients. The guidance provided in this document will be most useful if it is adapted to meet specific needs at country and programme levels.

It is recognized that some of the selected practice recommendations in this report will need to be reviewed in the light of new research as it becomes available. At appropriate intervals, WHO will update and add to the selected practice recommendations in this document. These recommendations are available on WHO's reproductive health web site (www.who.int/reproductive-health). The web site will also provide additional information determined by WHO to be relevant to these practice recommendations, pending the next formal consensus Working Group meeting. WHO encourages research to address the key unresolved issues noted in this document.

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Questions for which the Working Group provided recommendations

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1

When can a woman start combined oral contraceptives?

1. When can a woman start combined oral contraceptives (COCs)?

Having menstrual cycles

She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.

She can also start COCs at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Amenorrhoeic

She can start COCs at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Breastfeeding*

If she is more than 6 months postpartum and amenorrhoeic, she can start COCs as advised for other amenorrhoeic women.

If she is more than 6 months postpartum and her menstrual cycles have returned, she can start COCs as advised for other women having menstrual cycles.

* Women less than 6 weeks postpartum who are primarily breastfeeding should not use COCs. For women who are more than 6 weeks but less than 6 months postpartum and are primarily breastfeeding, use of COCs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Switching from another hormonal method

She can start COCs immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If her previous method was an injectable, she should start COCs when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.

She can also start immediately or at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Switching from an IUD (including hormonal)

She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.

She can also start at any other time, if it is reasonably certain that she is not pregnant.

If she has been sexually active in this menstrual cycle, and it has been more than 5 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.

If she has not been sexually active in this menstrual cycle and it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.

If she is amenorrhoeic or has irregular bleeding, she can start COCs as advised for other amenorrhoeic women.

Comments

The expert working group considered the risk of ovulation within the first 5 days of menstruation to be acceptably low. Suppression of ovulation was considered to be less reliable when starting COCs after day 5. Seven days of continuous COC use was deemed necessary to reliably prevent ovulation.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Systematic review question

How does starting COCs on different days of the menstrual cycle affect contraceptive efficacy and compliance? Level of evidence: II-1; indirect.

References from systematic review

1. Molloy BG, Coulson KA, Lee JM, Watters JK. “Missed pill” conception: fact or fiction? British Medical Journal Clinical Research Ed 1985;290:1474-5.

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Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. British Medical Journal 2000;321:1259-62.

2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

How quickly is protection reliably established by COCs?

Does starting each pill pack on a specific day of the week increase consistent, correct and continued use of COCs?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during COC use?

2

What can a woman do if she misses combined oral contraceptives?

2. What can a woman do if she misses COCs?

Missed any one active (hormonal) pill (Days 1 21)

She should:

Take the missed pill as soon as possible.

Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.

Continue taking the pills as usual, one each day.

She does not need any additional contraceptive protection.

Started a pack 2 or more days late

She should:

Start the new pack that day. (If she has chosen to start her packs on a particular day of the week, she can discard the missed pills so that she stays on her schedule).

Continue taking the pills as usual, one each day.

Abstain from sex or use additional contraceptive protection for the next 7 days.

She may wish to consider the use of emergency contraception if appropriate.

Missed any 2 4 of the first 7 active (hormonal) pills of the pack (Days 1 7)

She should:

Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).

Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.

Continue taking the pills as usual, one each day.

Abstain from sex or use additional contraceptive protection for the next 7 days.

She may wish to consider the use of emergency contraception if appropriate.

Missed any 2 4 of the middle 7 active (hormonal) pills in a pack (Days 8 14)

She should:

Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).

Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.

Continue taking the pills as usual, one each day.

She does not need any additional contraceptive protection.

Missed any 2 4 of the last 7 active (hormonal) pills in a pack (Days 15 21)

She should:

- Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).
- Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.
- Continue taking the active pills as usual, one each day.
- Discard the inactive pills and go straight to the next pack.

She does not need any additional contraceptive protection.

Missed 5 or more active (hormonal) pills in a row in any week (Days 1 21)

She should:

- Take the first missed pill as soon as possible. (If she wants to stay on her regular pill-taking schedule, she should then discard any other missed pills).
- Take the next pill at the usual time. This may mean taking 2 pills on the same day or even at the same time.
- Continue taking the active pills as usual, one each day.
- Discard the inactive pills and go straight to the next pack.
- Abstain from sex or use additional contraceptive protection for the next 7 days.

She may wish to consider the use of emergency contraception if appropriate.

Missed 1 or more inactive (non-hormonal) pills (Days 22 28 in 28-day pill packs)

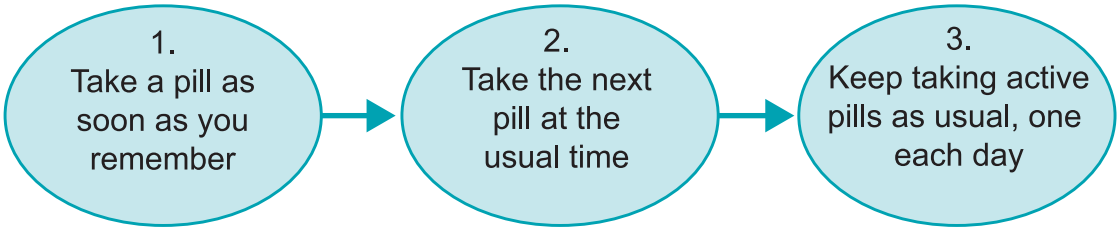
She should:

- Discard the missed inactive pill(s).
- Continue taking the pills as usual, one each day.
- Start a new pack as usual.

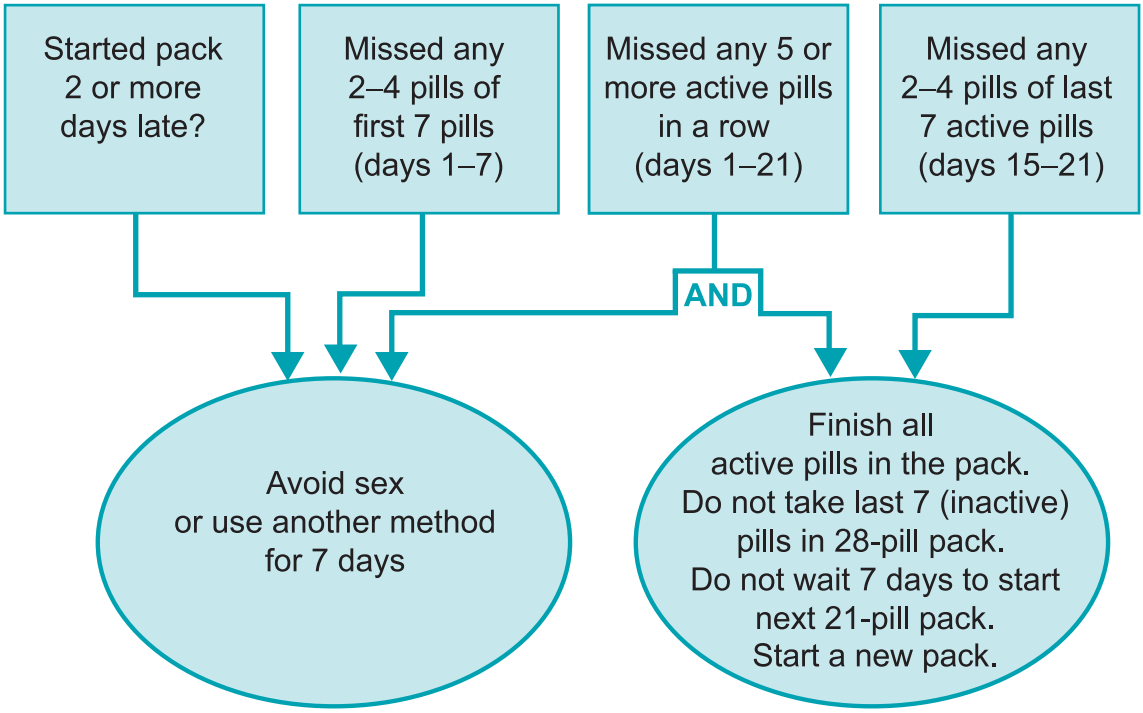
She does not need any additional contraceptive protection.

What to do if you miss one or more pills

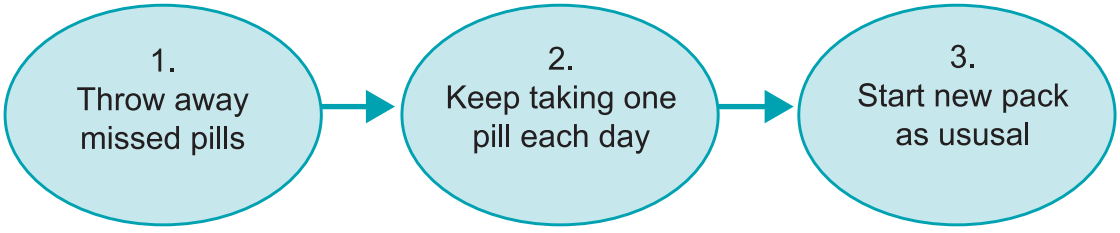
Every time you miss one or more active pills (days 1–21):



In these special cases, ALSO follow these special rules:



If you miss any of the 7 inactive pills (in a 28-pill pack only):



Source: Johns Hopkins University Bloomberg School of Public Health, Population Information Program

Comments

The expert working group considered the inconsistent or incorrect use of pills to be a major reason for unintended pregnancy. Seven days of continuous COC use was deemed necessary to reliably prevent ovulation.

Many women (including those whose pill packs are marked with the days of the week) follow a pill-taking schedule that involves starting on a certain day of the week. When such a woman misses pills, it is necessary to discard the missed pills if she is to maintain her schedule. Other women may prefer not to discard missed pills, but they may have menses at other than expected intervals.

The following 3 principles underlie the expert working group's recommendations:

1) It is important to take an active pill as soon as possible when pills have been missed.

2) If pills are missed, the chance that pregnancy will occur depends not only on how many pills were missed, but also on when those pills were missed. The risk of pregnancy is greatest when pills are missed at the beginning or at the end of the active pills, i.e., the hormone-free interval is extended beyond the normal 7 days.

3) If pills are missed in the first week of the cycle (including starting late), or if many pills are missed (5 or more), the woman should abstain from sex or use additional contraceptive protection for the next 7 days.

Systematic review question

What is the effect on contraceptive effectiveness when pills are missed on different days of the cycle? Level of evidence: I; indirect.

References from systematic review

1. Molloy BG, Coulson KA, Lee JM, Watters JK. "Missed pill" conception: fact or fiction? British Medical Journal Clinical Research Ed 1985;290:1474-5.

2. van der Spuy ZM, Sohnius U, Pienaar CA, Schall R. Gonadotropin and estradiol secretion during the week of placebo therapy in oral contraceptive pill users. Contraception 1990;42:597-609.

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4. van Heusden AM, Fauser BC. Activity of the pituitary-ovarian axis in the pill-free interval during use of low-dose combined oral contraceptives. Contraception 1999;59:237-43.

5. Hamilton C.J., Hoogland H.J. Longitudinal ultrasonographic study of the ovarian suppressive activity of a low-dose triphasic oral contraceptive during correct and incorrect pill intake. American Journal of Obstetrics & Gynecology 1989;161:1159-62.

6. Killick SR, Bancroft K, Oelbaum S, Morris J, Elstein M. Extending the duration of the pill-free interval during combined oral contraception. Advances in Contraception 1990;6:33-40.

7. Landgren BM, Diczfalusy E. Hormonal consequences of missing the pill during the first two days of three consecutive artificial cycles. Contraception 1984;29:437-46.

8. Elomaa K, Rolland R, Brosens I, Moorrees M, Deprest J, Tuominen J et al. Omitting the first oral contraceptive pills of the cycle does not automatically lead to ovulation. American Journal of Obstetrics & Gynecology 1998;179:41-6.

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14. Spona J, Elstein M, Feichtinger W, Sullivan H, Ludicke F, Muller U. Shorter pill-free interval in combined oral contraceptives decreases follicular development. Contraception 1996;54:71-7.

15. Sullivan H, Furniss H, Spona J, Elstein M. Effect of 21-day and 24-day oral contraceptive regimens containing gestodene (60 microg) and ethinyl estradiol (15 microg) on ovarian activity. Fertility & Sterility 1999;72:115-20.

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17. Wang E, Shi S, Cekan SZ, Landgren BM, Diczfalusy E. Hormonal consequences of “missing the pill”. Contraception 1982;26:545-66.

18. Nuttall ID, Elstein M, McCafferty E, Seth J, Cameron ED. The effect of ethinyl estradiol 20 mcg and levonorgestrel 250 mcg on the pituitary-ovarian function during normal tablet-taking and when tablets are missed. Contraception 1982;26:121-35.

19. Morris SE, Grume GV, Cameron ED, Buckingham MS, Everitt JM, Elstein M. Studies on low dose oral contraceptives: plasma hormone changes in relation to deliberate pill (‘Microgynon 30’) omission. Contraception 1979;20:61-9.

Other key references

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2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

How do the number and timing of missed COCs affect the risk of pregnancy, and are there substantial variations among individuals or populations?

How well do COC users understand and follow pill-taking instructions, including use of back-up contraception after missed pills?

Would shortening the hormone-free interval significantly decrease pregnancy rates?

Are regimens for missed 30-35 mcg ethinylestradiol COCs appropriate for COCs with lower doses of estrogen, especially with regard to the need for back-up protection?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during COC use?

What are the most effective counselling and other communication strategies for maximizing consistent, correct and continued use of COCs?

3

What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives or progestogen-only pills ?

3. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives (COCs) or progestogen-only pills (POPs)?

Vomiting (for any reason) within 2 hours after taking an active (hormonal) pill.

She should take another active pill.

Severe vomiting or diarrhoea for more than 24 hours.

She should continue taking pills (if she can) despite her discomfort.

If severe vomiting or diarrhoea continues for 2 or more days, she should follow the procedures for missed pills.

Comments

The expert working group found no direct evidence to address this question but considered the effects of vomiting or diarrhoea to be similar to those of missing pills.

Systematic review question

How does vomiting or diarrhoea during COC or POP use affect contraceptive effectiveness?
Level of evidence: I; indirect.

References from systematic review

1. Elomaa K, Ranta S, Tuominen J, Lahteenmaki P. Charcoal treatment and risk of escape ovulation in oral contraceptive users. Human Reproduction 2001;16:76-81.

Key unresolved issues

Is the effect of severe vomiting and/or diarrhoea sufficient to warrant use of the missed pill regimen?

4

When can a woman start combined injectable contraceptives?

4. When can a woman start combined injectable contraceptives (CICs)?

Note: These recommendations are based on information on combined injectables containing medroxyprogesterone acetate and estradiol cypionate (Cyclofem/Lunelle) but also apply to combined injectables containing norethisterone enantate and estradiol valerate (Mesigyna).

Having menstrual cycles

She can have the first CIC injection within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.

She can also have the first injection at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Amenorrhoeic

She can have the first injection at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Breastfeeding*

If she is more than 6 months postpartum and amenorrhoeic, she can start CICs as advised for other amenorrhoeic women.

If she is more than 6 months postpartum and her menstrual cycles have returned, she can have her first injection as advised for other women having menstrual cycles.

* Women less than 6 weeks postpartum who are primarily breastfeeding should not use CICs. For women who are more than 6 weeks but less than 6 months postpartum and are primarily breastfeeding, use of CICs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Switching from another hormonal method

She can have the first injection immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If her previous method was another injectable, she should have the CIC injection when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

She can have the first injection immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.

If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Switching from an IUD (including hormonal)

She can have the first injection within 7 days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.

She can also start at any other time, if it is reasonably certain that she is not pregnant.

If she has been sexually active in this menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.

If she has not been sexually active in this menstrual cycle and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.

If she is amenorrhoeic or has irregular bleeding, she can have the injection as advised for other amenorrhoeic women.

Comments

The expert working group considered that an injection given up to day 7 of the menstrual cycle results in a low risk of an ovulatory cycle that could lead to pregnancy.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Systematic review question

How does starting CICs on different days of the menstrual cycle affect contraceptive effectiveness? Level of evidence: I; indirect.

References from systematic review

1. Petta CA, Hays M, Brache V, Massai R, Hua Y, Alvarez Sanchez F et al. Delayed first injection of the once-a-month injectable contraceptive containing 25 mg of medroxyprogesterone acetate and 5 mg E(2) cypionate: effects on ovarian function. Fertility & Sterility 2001;75:744-8.

Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. British Medical Journal 2000;321:1259-62.

2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

How quickly is protection reliably established by CICs?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during CIC use?

5

When can a woman have repeat combined injectable contraceptive injections?

5. When can a woman have repeat CIC injections?

Note: These recommendations are based on information on combined injectables containing medroxyprogesterone acetate and estradiol cypionate (Cyclofem/Lunelle) but also apply to combined injectables containing norethisterone enantate and estradiol valerate (Mesigyna).

Reinjection interval

Provide repeat CIC injections every 4 weeks.

Early for an injection

When the reinjection interval cannot be adhered to, the repeat injection can be given up to 7 days early but may disrupt bleeding patterns.

Late for an injection

When the reinjection interval cannot be adhered to, the repeat injection can be given up to 7 days late without requiring additional contraceptive protection.

If she is more than 7 days late for an injection, she can have the injection, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days. She may wish to consider the use of emergency contraception if appropriate.

Comments

The risk of ovulation was considered by the expert working group to be minimal during the early part of the second month after the last injection.

Systematic review question

How soon after the last CIC injection do ovulation and fertility return?
Level of evidence: II-3; indirect.

References from systematic review

1. Aedo AR, Landgren BM, Johannisson E, Diczfalusy E. Pharmacokinetic and pharmacodynamic investigations with monthly injectable contraceptive preparations. Contraception 1985;31:453-69.

2. Garza-Flores J. A multi-centered pharmacokinetic, pharmacodynamic study of once-a-month injectable contraceptives. I. Different doses of HRP112 and of DepoProvera. Contraception 1987;36:441-57.

3. Bassol S, Hernandez C, Nava MP, Trujillo AM, Luz de la Cruz D. A comparative study on the return to ovulation following chronic use of once-a-month injectable contraceptives. Contraception 1995;51:307-11.

4. Rahimy MH, Ryan KK. Lunelle monthly contraceptive injection (medroxyprogesterone acetate and estradiol cypionate injectable suspension): assessment of return of ovulation after three monthly injections in surgically sterile women. Contraception 1999;60:189-200.

5. Bahamondes L, Lavin P, Ojeda G, Petta CA, Diaz J, Maradiegue E et al. Return to fertility after discontinuation of the once a month injectable contraceptive Cyclofem. Contraception 1997;55:307-10.

Key unresolved issues

What is the maximum time between injections that maintains effectiveness of CICs?

What are the most effective counselling and communication strategies for increasing adherence to CIC reinjection intervals?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during CIC use?

6

6

When can a woman start progestogen-only pills?

6. When can a woman start progestogen-only pills?

Having menstrual cycles

She can start progestogen-only pills (POPs) within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.

She can also start POPs at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 2 days.

Amenorrhoeic

She can start POPs at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 2 days.

Breastfeeding*

If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can start POPs at any time. If she is fully or nearly fully breastfeeding no additional contraceptive protection is needed.

If she is more than 6 weeks postpartum and her menstrual cycles have returned, she can start POPs as advised for other women having menstrual cycles.

* For women who are less than 6 weeks postpartum and primarily breastfeeding, use of POPs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Switching from another hormonal method

She can start POPs immediately, if she has been using her hormonal method consistently and correctly, or if it is otherwise reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If her previous method was an injectable, she should start POPs when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

She can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.

She can also start immediately or at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 2 days.

Switching from an IUD (including hormonal)

She can start POPs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.

She can also start at any other time, if it is reasonably certain that she is not pregnant.

If she has been sexually active in this menstrual cycle, and it has been more than 5 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.

If she has not been sexually active in this menstrual cycle and it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 2 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.

If she is amenorrhoeic or has irregular bleeding, she can start POPs as advised for other amenorrhoeic women.

Comments

The expert working group considered the risk of ovulation when starting POPs within the first 5 days of menstruation to be acceptably low. Suppression of ovulation was considered to be less reliable when starting after day 5. An estimated 48 hours of POP use was deemed necessary to achieve the contraceptive effects on cervical mucus.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Systematic review question

How does starting POPs on different days of the menstrual cycle affect contraceptive efficacy?

References from systematic review

No studies identified.

Other key references

1. McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6 Suppl 1):S1-195.

2. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. British Medical Journal 2000;321:1259-62.

3. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

How quickly is protection reliably established by POPs?

Does starting each pill pack on a specific day of the week increase consistent, correct and continued use of POPs?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during POP use?

7

What can a woman do if she misses progestogen-only pills?

7. What can a woman do if she misses progestogen-only pills (POPs)?

Having menstrual cycles (including those who are breastfeeding) AND missed one or more pills by more than 3 hours

She should:

Take 1 pill as soon as possible.

Continue taking the pills as usual, one each day.

Abstain from sex or use additional contraceptive protection for the next 2 days.

She may wish to consider the use of emergency contraception if appropriate.

Breastfeeding and amenorrhoeic AND missed one or more pills by more than 3 hours

She should:

Take 1 pill as soon as possible.

Continue taking the pills as usual, one each day.

If she is less than 6 months postpartum, no additional contraceptive protection is needed.

Comments

The expert working group considered the inconsistent or incorrect use of pills to be a major reason for unintended pregnancy and highlighted the importance of taking POPs at approximately the same time each day. An estimated 48 hours of POP use was deemed necessary to achieve the contraceptive effects on cervical mucus.

Systematic review question

What is the effect on contraceptive effectiveness when progestogen-only pills are missed on different days of the cycle?

References from systematic review

No studies identified.

Other key references

1. McCann MF, Potter LS. Progestin-only oral contraception: a comprehensive review. Contraception 1994;50(6 Suppl 1):S1-195.

Key unresolved issues

How do the number and timing of missed POPs affect the risk of pregnancy?

When POPs are missed, is 48 hours of backup fully sufficient to re-establish contraceptive protection, and do requirements for back-up contraception vary depending on the number of missed pills?

How well do POP users understand and follow pill-taking instructions, including use of back-up contraception after missed pills?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during POP use?

What are the most effective counselling and communication strategies for maximizing consistent, correct and continued use of POPs?

8

What can a woman do if she vomits after taking emergency contraceptive pills?

8. What can a woman do if she vomits after taking emergency contraceptive pills (ECPs)?

Vomiting within 2 hours after taking a dose of pills

She should take another ECP dose as soon as possible. If the ECPs are combined estrogen-progestogen pills (COCs), she may want to use an anti-emetic before taking the second dose.

If vomiting continues, a repeat ECP dose can be given vaginally.

Comments

The expert working group noted that progestogen-only ECPs are less likely to cause nausea and vomiting than are combined estrogen-progestogen ECPs.

Systematic review question

How does vomiting or diarrhoea during ECP use affect contraceptive effectiveness?

References from systematic review

No studies identified.

Key unresolved issues

Does vomiting within 2 hours after taking ECPs result in a meaningful decrease in effectiveness?

9

When can a woman start progestogen-only injectables – DMPA or NET-EN?

9. When can a woman start progestogen-only injectables – DMPA or NET-EN?

Note: These recommendations are based on information on an injectable containing depot medroxyprogesterone acetate (DMPA) but apply also to norethisterone enantate (NET-EN).

Having menstrual cycles

She can have the first progestogen-only injection within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.

She can also have the first injection at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Amenorrhoeic

She can have the first injection at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Breastfeeding*

If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can have her first injection at any time. If she is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.

If she is more than 6 weeks postpartum and her menstrual periods have returned, she can have her first injection as advised for other women having menstrual cycles.

* For women who are less than 6 weeks postpartum and primarily breastfeeding, use of POIs is not usually recommended unless other more appropriate methods are not available or not acceptable.

Switching from another hormonal method

She can have the first injection immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If her previous method was another injectable, she should have the progestogen-only injection when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

She can have the first injection immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.

If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Switching from an IUD (including hormonal)

She can have the first injection within 7 days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.

She can also start at any other time, if it is reasonably certain that she is not pregnant.

If she has been sexually active in this menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.

If she has not been sexually active in this menstrual cycle and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.

If she is amenorrhoeic or has irregular bleeding, she can have the injection as advised for other amenorrhoeic women.

Comments

The expert working group considered that an injection given up to day 7 of the menstrual cycle results in a low risk of an ovulatory cycle that could lead to pregnancy.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Whereas an estimated 48 hours of POP use was deemed necessary to achieve contraceptive effect on cervical mucus, the time required for progestogen-only injectables to exert such an effect was uncertain.

Systematic review question

How does starting progestogen-only injectables on different days of the menstrual cycle affect contraceptive effectiveness? Level of evidence: II-1; indirect.

References from systematic review

1. Siriwongse T, Snidvongs W, Tantayaporn P, Leepipatpaiboon S. Effect of depo-medroxyprogesterone acetate on serum progesterone levels when administered on various cycle days. Contraception 1982;26:487-93.

2. Petta CA, Faundes A, Dunson TR, Ramos M, DeLucio M, Faundes D et al. Timing of onset of contraceptive effectiveness in Depo-Provera users: Part I. Changes in cervical mucus. Fertility & Sterility 1998;69:252-7.

3. Petta CA, Faundes A, Dunson TR, Ramos M, DeLucio M, Faundes D et al. Timing of onset of contraceptive effectiveness in Depo-Provera users. II. Effects on ovarian function. Fertility & Sterility 1998; 70:817-20.

Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. British Medical Journal 2000;321:1259-62.

2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

How quickly is protection reliably established by injections of DMPA and NET-EN?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during POI use?

10

When can a woman have repeat progestogen-only injectables – DMPA or NET-EN?

10. When can a woman have repeat progestogen-only injectables DMPA or NET-EN ?

Reinjection interval

Provide repeat DMPA injections every 3 months.

Provide repeat NET-EN injections every 2 months.

Early for an injection

The repeat injection for DMPA and NET-EN can be given up to 2 weeks early.

Late for an injection

The repeat injection for DMPA and NET-EN can be given up to 2 weeks late without requiring additional contraceptive protection.

If she is more than 2 weeks late for a DMPA or NET-EN repeat injection, she can have the injection, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days. She may wish to consider the use of emergency contraception if appropriate.

Switching between DMPA and NET-EN

Using DMPA and NET-EN injections interchangeably is not recommended.

If it becomes necessary to switch from one to the other, the switch should be made at the time the repeat injection would have been given.

For a repeat POI when the previous injectable type and/or timing of injection is unknown

She can have the injection if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

She may wish to consider the use of emergency contraception if appropriate.

Comments

The expert working group considered the risk of ovulation to be minimal within 2 weeks following the time for a repeat injection (3 months for DMPA and 2 months for NET-EN).

The mechanisms of action, the medical eligibility criteria, and the side-effects of DMPA and NET-EN are similar. Therefore it is safe to stop using one and start using the other.

Whereas an estimated 48 hours of POP use was deemed necessary to achieve contraceptive effect on cervical mucus, the time required for progestogen-only injectables to exert such an effect was uncertain.

Systematic review question

How soon after the last injection of a progestogen-only injectable do ovulation and fertility return? Level of evidence: II-3; indirect.

References from systematic review

1. Pardthaisong T. Return of fertility after the use of the injectable contraceptive Depo Provera: Updated data analysis. Journal of Biosocial Science 1984;16:23-34.

2. Anonymous. ICMR (Indian Council of Medical Research) Task Force on Hormonal Contraception. Return of fertility following discontinuation of an injectable contraceptive—norethisterone oenanthate (NET-EN) 200 mg dose. Contraception 1986;34:573-82.

3. Ortiz A, Hiroi M, Stanczyk FZ, Goebelsmann U, Mishell DR. Serum medroxyprogesterone acetate (MPA) concentrations and ovarian function following intramuscular injection of Depo-MPA. Journal of Clinical Endocrinology and Metabolism 1977;44:32-8.

4. Fotherby K, Saxena B, Shrimanker K, Hingorani V, Takker D, Diczfalusy E et al. A preliminary pharmacokinetic and pharmacodynamic evaluation of depot-medroxyprogesterone acetate and norethisterone oenanthate. Fertility & Sterility 1980;34:131-9.

5. Bassol S, Garza-Flores J, Cravioto MC, Diaz-Sanchez V, Fotherby K, Lichtenberg R et al. Ovarian function following a single administration of depo-medroxy progesterone acetate (DMPA) at different doses. Fertility & Sterility 1984;42:216-22.

6. Lan PT, Aedo AR, Landgren BM, Johannisson E, Diczfalusy E. Return of ovulation following a single injection of depo-medroxyprogesterone acetate: a pharmacokinetic and pharmaco-dynamic study. Contraception 1984;29:1-18.

7. Saxena BN, Dusitsin N, Tankeyoon M, Chaudhury RR. Return of ovulation after the cessation of depot-medroxy progesterone acetate treatment in Thai women. Journal of the Medical Association of Thailand 1980;63:66-9.

8. Garza-Flores J, Cardenas S, Rodriguez V, Cravioto MC, Diaz-Sanchez V. Return to ovulation following the use of long-acting injectable contraceptives: a comparative study. Contraception 1985;31:361-6.

Key unresolved issues

How common is switching between DMPA and NET-EN and why does switching occur?

How accurately do ultrasound findings, hormonal measurements and evaluation of cervical mucus predict the risk of pregnancy during use of progestogen-only injectables?

What is the maximum time between injections that maintains effectiveness of progestogen-only injectables?

What are the most effective counselling and other communication strategies for increasing adherence to reinjection intervals for progestogen-only injectables?

11

What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable – DMPA or NET-EN?

11

11. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable – DMPA or NET-EN?

Amenorrhoea

Amenorrhoea does not require any medical treatment. Counselling is sufficient.

If she still finds amenorrhoea unacceptable, discontinue the injectable. Help her choose another method.

Spotting or light bleeding

Spotting or light bleeding is common during POI use, particularly in the first injection cycle, and is not harmful.

In women with persistent spotting or bleeding, or women with bleeding after a period of amenorrhoea, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.

If STI or pelvic inflammatory disease (PID) is diagnosed, she can continue her injections while receiving treatment, and be counselled on condom use.

If no gynaecologic problems are found, and she finds the bleeding unacceptable, discontinue the injectable. Help her choose another method.

Heavy or prolonged bleeding (more than 8 days or twice as much as her usual menstrual period)

Explain that heavy or prolonged bleeding is common in the first injection cycle.

If heavy or prolonged bleeding persists, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.

If the bleeding becomes a threat to the health of the woman, or it is not acceptable to her, discontinue the injectable. Help her choose another method.

To prevent anaemia, provide an iron supplement and/or encourage foods containing iron.

Comments

The expert working group noted that menstrual abnormalities are common with use of POIs and that counselling about such abnormalities before initiation of POI use is essential to alleviate concerns and encourage continuation of the method.

The group reviewed the limited available data regarding treatment and determined that treatment for light or heavy bleeding with estrogens or non-steroidal anti-inflammatory drugs (NSAIDs) is likely to be of short-term or no benefit.

Systematic review question

What is the evidence for effective treatment regimens for bleeding abnormalities during POI use? Level of evidence: I; direct.

References from systematic review

1. Parker RA, McDaniel EB. The use of quinesterol for the control of vaginal bleeding irregularities caused by DMPA. Contraception 1980;22:1-7.

2. Sapire KE. A study of bleeding patterns with two injectable contraceptives given post-partum and the effect of two nonhormonal treatments. Advances in Contraception 1991;7:379-87.

3. Said S, Sadek W, Rocca M, Koetsawang S, Kirwat O, Piya-Anant M. Clinical evaluation of the therapeutic effectiveness of ethinyl oestradiol and oestrone sulphate on prolonged bleeding in women using depot medroxyprogesterone acetate for contraception. World Health Organization, Special Programme of Research, Development and Research Training in Human Reproduction, Task Force on Long-acting Systemic Agents for Fertility Regulation. Human Reproduction 1996;11:1-13.

Key unresolved issues

What are the mechanisms underlying progestogen-only injectable-associated bleeding abnormalities and how can they best be treated?

What are the most effective counselling and other communication strategies for assisting women with bleeding abnormalities?

12

When can a woman start using an implant?

12

12. When can a woman start using an implant?

Note: These recommendations are based on information from, and relate to, approved levonorgestrel implants (Norplant and Jadelle). The extent to which they apply to etonogestrel implants is not known. The product labelling for an etonogestrel implant (Implanon) states that the implant should be inserted between days 1–5, but at the latest on day 5 of the woman's natural menstrual cycle.

Having menstrual cycles

She can have the implant inserted within 7 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.

She can also have the implant inserted at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Amenorrhoeic

She can have the implant inserted at any time, if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Breastfeeding*

If she is between 6 weeks and 6 months postpartum and amenorrhoeic, she can have the implant inserted at any time. If she is fully or nearly fully breastfeeding, no additional contraceptive protection is needed.

If she is more than 6 weeks postpartum and her menstrual cycles have returned, she can have the implant inserted as advised for other women having menstrual cycles.

* For women who are less than 6 weeks postpartum and primarily breastfeeding, use of progestogen-only implants is not usually recommended unless other more appropriate methods are not available or not acceptable.

Switching from another hormonal method

The implant can be inserted immediately, if she has been using her hormonal method consistently and correctly, or if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If her previous method was an injectable, she should have the implant inserted when the repeat injection would have been given. No additional contraceptive protection is needed.

Switching from a non-hormonal method (other than the IUD)

She can have the implant inserted immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period.

If she is within 7 days of the start of her menstrual bleeding, no additional contraceptive protection is needed.

If it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

Switching from an IUD (including hormonal)

She can have the implant inserted within 7 days after the start of menstrual bleeding. No additional contraceptive protection is needed. The IUD can be removed at that time.

She can also start at any other time, if it is reasonably certain that she is not pregnant.

If she has been sexually active in this menstrual cycle, and it has been more than 7 days since menstrual bleeding started, it is recommended that the IUD be removed at the time of her next menstrual period.

If she has not been sexually active in this menstrual cycle and it has been more than 7 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days. If that additional protection is to be provided by the IUD she is using, it is recommended that this IUD be removed at the time of her next menstrual period.

If she is amenorrhoeic or has irregular bleeding, she can have the implant inserted as advised for other amenorrhoeic women.

Comments

The expert working group considered that an implant inserted up to day 7 of the menstrual cycle results in a low risk of an ovulatory cycle that could lead to pregnancy.

The need for additional contraceptive protection among those switching from another hormonal method will depend on the previous method used.

There was some concern about the risk of pregnancy when removing an IUD within a cycle where there has already been intercourse. That concern led to the recommendation that the IUD be left in place until the next menstrual period.

Whereas an estimated 48 hours of POP use was deemed necessary to achieve contraceptive effect on cervical mucus, the time required for levonorgestrel implants to exert such an effect was uncertain.

Systematic review question

How does starting implants on different days of the cycle affect contraceptive effectiveness?
Level of evidence: II-3; indirect.

References from systematic review

1. Brache V, Alvarez F, Faundes A, Cochon L, Thevenin F. Effect of preovulatory insertion of Norplant implants over luteinizing hormone secretion and follicular development. Fertility & Sterility 1996;65:1110-4.

2. Dunson TR, Blumenthal PD, Alvarez F, Brache V, Cochon L, Dalberth B et al. Timing of onset of contraceptive effectiveness in Norplant implant users. Part I. Changes in cervical mucus. Fertility & Sterility 1998;69:258-66.

3. Brache V, Blumenthal PD, Alvarez F, Dunson TR, Cochon L, Faundes A. Timing of onset of contraceptive effectiveness in Norplant implant users. II. Effect on the ovarian function in the first cycle of use. Contraception 1999;59:245-51.

Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. British Medical Journal 2000;321:1259-62.

2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

How many days after the start of the menstrual cycle can etonogestrel implants be inserted and be effective during that cycle?

How quickly is protection reliably established by etonogestrel implants?

How quickly does fertility return once etonogestrel implants are removed?

13

What can be done if a woman experiences menstrual abnormalities when using implants?

13. What can be done if a woman experiences menstrual abnormalities when using implants?

Note: These recommendations are based on information from, and relate to, approved levonorgestrel implants (Norplant/Jadelle). The extent to which the treatment recommendations apply to etonogestrel implants (Implanon) is not known.

Amenorrhoea

Amenorrhoea does not require any medical treatment. Counselling is sufficient.

If she still finds amenorrhoea unacceptable, the implant should be removed. Help her choose another contraceptive method.

Spotting or light bleeding

Spotting or light bleeding is common during implant use, particularly in the first year, and is not harmful.

In women with persistent spotting or bleeding, or women with bleeding after a period of amenorrhoea, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.

If STI or PID is diagnosed, she can continue using implants while receiving treatment and be counselled on condom use.

If no gynaecologic problems are found, and she desires treatment, non-hormonal and hormonal options are available:

Non-hormonal: non-steroidal anti-inflammatory drugs (NSAIDs)

Hormonal (if medically appropriate): low-dose COCs or ethinylestradiol

If she does not desire treatment or the treatment is not effective, and she finds the bleeding unacceptable, the implants should be removed. Help her choose another method.

Heavy or prolonged bleeding (more than 8 days or twice as much as her usual menstrual period)

Exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.

If no gynaecologic problems are found, and she desires treatment, non-hormonal and hormonal options are available:

Non-hormonal: non-steroidal anti-inflammatory drugs (NSAIDs)

Hormonal (if medically appropriate): COCs or ethinylestradiol

If she does not desire treatment or the treatment is not effective, and the bleeding becomes a threat to her health or is not acceptable to her, the implant should be removed. Help her choose another method.

Comments

The expert working group noted that menstrual abnormalities are common with use of implants and that counselling about such abnormalities before initiation of implant use is essential to alleviate concerns and encourage continuation of the method.

The group reviewed the limited available data regarding treatment for light or heavy bleeding and determined that the following regimens are modestly effective:

Non-hormonal methods: non-steroidal anti-inflammatory drugs (NSAIDs):

Ibuprofen – 800 mg 3 times a day for 5 days

Mefenamic acid – 500 mg 2 times a day for 5 days

Hormonal methods:

Low-dose COCs – 30 µg ethinylestradiol 150 µg levonorgestrel a day for 21 days

COCs – 50 µg ethinylestradiol 250 µg levonorgestrel a day for 21 days

Ethinylestradiol – 50 µg for 20 days

Systematic review question

What is the evidence for effective treatment regimens for bleeding abnormalities during implant use? Level of evidence: I; direct.

References from systematic review

1. Diaz S, Croxatto HB, Pavez M, Belhadj H, Stern J, Sivin I. Clinical assessment of treatments for prolonged bleeding in users of Norplant implants. Contraception 1990;42:97-109.

2. Alvarez-Sanchez F, Brache V, Thevenin F, Cochon L, Faundes A. Hormonal treatment for bleeding irregularities in Norplant implant users. American Journal of Obstetrics & Gynecology 1996;174:919-22.

3. Witjaksono J, Lau TM, Affandi B, Rogers PA. Oestrogen treatment for increased bleeding in Norplant users: preliminary results. Human Reproduction 1996;11:109-14.

4. Boonkasemsanti W, Reinprayoon D, Pruksananonda K, Niruttisard S, Triratanachat S, Leepipatpaiboon S et al. The effect of transdermal oestradiol on bleeding patterns, hormonal profiles and sex steroid receptor distribution in the endometrium of Norplant users. Human Reproduction 1996;11:115-23.

5. Cheng L, Zhu H, Wang A, Ren F, Chen J, Glasier A. Once a month administration of mifepristone improves bleeding patterns in women using subdermal contraceptive implants releasing levonorgestrel. Human Reproduction 2000;15:1969-72.

6. Subakir SB, Setiadi E, Affandi B, Pringgoutomo S, Freisleben HJ. Benefits of vitamin E supplementation to Norplant users – in vitro and in vivo studies. Toxicology 2000;148: 173-8.

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Key unresolved issues

What are the mechanisms underlying etonogestrel and levonorgestrel implant-associated bleeding abnormalities and how can they best be treated?

What are the most effective counselling and other communication strategies for assisting women with bleeding abnormalities?

14

When can a copper-bearing IUD be inserted?

14

14. When can a copper-bearing IUD be inserted?

Having menstrual cycles

A woman can have a copper-bearing IUD inserted any time within the first 12 days after the start of menstrual bleeding, at her convenience, not just during menstruation. No additional contraceptive protection is needed.

The copper-bearing IUD can also be inserted at any other time during the menstrual cycle, at her convenience, if it is reasonably certain that she is not pregnant. No additional contraceptive protection is needed.

Switching from another method

She can have the copper-bearing IUD inserted immediately, if it is reasonably certain that she is not pregnant. There is no need to wait for her next menstrual period. No additional contraceptive protection is needed.

Comments

The expert working group determined that the probability of an existing pregnancy is extremely low before day 12 of the menstrual cycle, based on the extremely low risk of ovulation before day 8 and the 5-day emergency contraceptive effect of copper-bearing IUDs.

The recommendation of the expert working group for copper-bearing IUDs does not apply to hormonal IUDs because the emergency contraceptive effect of copper-bearing IUDs cannot be presumed to apply to hormonal IUDs. Further, in the event of pregnancy there may be added risks to the fetus due to the hormonal exposure.

Systematic review question

How does inserting an IUD on different days of the menstrual cycle affect contraceptive safety, effectiveness, and compliance? Level of evidence: II-3; indirect.

References from systematic review

1. White MK, Ory HW, Rooks JB, Rochat RW. Intrauterine device termination rates and the menstrual cycle day of insertion. Obstetrics & Gynecology 1980;55:220-4.

2. Goldstuck ND. Pain response following insertion of a Gravigard (Copper-7) intrauterine contraceptive device in nulliparous women. International Journal of Fertility 1981;26:53-6.

3. Goldstuck ND, Matthews ML. A comparison of the actual and expected pain response following insertion of an intrauterine contraceptive device. Clinical Reproduction & Fertility 1985;3:65-71.

Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. British Medical Journal 2000;321:1259-62.

2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

How quickly is protection reliably established for hormonal, copper-bearing IUDs?

15

What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?

15

15. What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?

Spotting or light bleeding between menstrual periods

Spotting or light bleeding is common during the first 3–6 months of copper-bearing IUD use. It is not harmful and usually decreases over time.

If she desires treatment, a short course of non-steroidal anti-inflammatory drugs (NSAIDs) may be given during the days of bleeding.

In women with persistent spotting and bleeding, exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.

If no gynaecologic problems are found, and she finds the bleeding unacceptable, remove the IUD and help her choose another method.

Heavier or longer menstrual bleeding than with normal menstrual periods

Heavier and longer menstrual bleeding is common during the first 3–6 months of copper-bearing IUD use. Usually this is not harmful, and bleeding usually becomes lighter over time.

The following treatment may be offered during the days of menstrual bleeding:

- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Tranexamic acid (a haemostatic agent)

Aspirin should NOT be used.

Exclude gynaecologic problems when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer for care.

If the bleeding continues to be very heavy or prolonged, especially if there are clinical signs of anaemia, or if she finds the bleeding unacceptable, remove the IUD and help her choose another method.

To prevent anaemia, provide an iron supplement and/or encourage foods containing iron.

Comments

The expert working group noted that menstrual abnormalities are common in the first 3–6 months of IUD use and concluded that treatment during the days of bleeding can sometimes be effective. The group indicated that aspirin should not be used to treat IUD-related menstrual bleeding because it may worsen the problem.

Systematic review question

What is the evidence for effective treatment regimens for menstrual abnormalities during IUD use? Level of evidence: I; direct.

References from systematic review

1. Roy S, Shaw ST, Jr. Role of prostaglandins in IUD-associated uterine bleeding—effect of a prostaglandin synthetase inhibitor (ibuprofen). Obstetrics & Gynecology 1981;58:101-6.

2. Toppozada M, El-Attar A, El-Ayyat MA, Khamis Y. Management of uterine bleeding by PGs or their synthesis inhibitors. Advances in Prostaglandin and Thromboxane Research 1980;8:1459-63.

3. Toppozada M, Anwar M, Abdel Rahman H, Gaweesh S. Control of IUD-induced bleeding by three nonsteroidal anti-inflammatory drugs. Contraceptive Delivery Systems 1982;3:117-25.

4. Yarkoni S, Anteby SO. Treatment of IUD related menorrhagia by indomethacin. Clinical & Experimental Obstetrics & Gynecology 1984;11:120-2.

5. Anteby SO, Yarkoni S, Ever HP. The effect of a prostaglandin synthetase inhibitor, indomethacin, on excessive uterine bleeding. Clinical & Experimental Obstetrics & Gynecology 1985;12:60-3.

6. Di Lieto A, Catalano D, Miranda L, Paladini A. Action of a prostaglandin synthetase inhibitor on IUD associated uterine bleeding. Clinical & Experimental Obstetrics & Gynecology 1987;14:41-4.

7. Davies AJ, Anderson AB, Turnbull AC. Reduction by naproxen of excessive menstrual bleeding in women using intrauterine devices. Obstetrics & Gynecology 1981;57:74-8.

8. Ylikorkala O, Viinikka L. Comparison between antifibrinolytic and antiprostaglandin treatment in the reduction of increased menstrual blood loss in women with intrauterine contraceptive devices. British Journal of Obstetrics & Gynaecology 1983;90:78-83.

9. Tauber PF, Kloppel A, Goodpasture JC, Burns J, Ludwig H, Zaneveld LJ. Reduced menstrual blood loss by release of an antifibrinolytic agent from intrauterine contraceptive devices. American Journal of Obstetrics & Gynecology 1981;140:322-8.

10. Pedron N, Lozano M, Gallegos AJ. The effect of acetylsalicylic acid on menstrual blood loss in women with IUDs. Contraception 1987;36:295-303.

11. Randic L, Balogh SA. The effect of hydrogel on the reduction of bleeding associated with IUD use: a comparative study of the plain and Hydron-coated Spring Coil. Contraceptive Delivery Systems 1983;4:301-10.

Key unresolved issues

What are the mechanisms underlying IUD-associated bleeding abnormalities and how do they vary among hormonal and copper-bearing devices?

How can bleeding abnormalities with hormonal and copper-bearing devices best be treated?

What are the most effective counselling and other communication strategies for assisting women with bleeding abnormalities?

16

What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?

16

16. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?

Pelvic inflammatory disease (PID)

Treat the PID using appropriate antibiotics.

There is no need for removal of the copper-bearing IUD if she wishes to continue its use.

If she does not want to keep the IUD, remove it after antibiotic treatment has been started.

If the IUD is removed, she can consider using emergency contraceptive pills if appropriate.

If the infection does not improve, generally the course would be to remove the IUD and continue antibiotics. If the IUD is not removed, antibiotics should also be continued. In both circumstances, her health should be closely monitored.

Provide comprehensive management for STIs, including counselling about condom use.

Comments

The expert working group concluded that removing the IUD provides no additional benefit once PID is being treated with appropriate antibiotics.

Systematic review question

Should the IUD be removed or left in place if the IUD user is diagnosed with PID?
Level of evidence: I; direct.

References from systematic review

1. Larsson B, Wennergren M. Investigation of a copper-intrauterine device (Cu-IUD) for possible effect on frequency and healing of pelvic inflammatory disease. Contraception 1977;15:143-9.

2. Söderberg G, Lindgren S. Influence of a intrauterine device on the course of an acute salpingitis. Contraception 1981;24:137-43.

3. Teisala K. Removal of an intrauterine device and the treatment of acute pelvic inflammatory disease. Annals of Medicine 1989;21:63-5.

Key unresolved issues

Are the clinical course of PID and the long-term sequelae of PID (infertility, ectopic pregnancy and chronic pain) influenced by the decision to remove or not remove an IUD once PID is diagnosed and appropriately treated?

17

What should be done if a woman using a copper-bearing IUD is found to be pregnant?

17. What should be done if a woman using a copper-bearing IUD is found to be pregnant?

Copper-bearing IUD user is found to be pregnant

Exclude ectopic pregnancy.

Explain that she is at risk of second trimester miscarriage, pre-term delivery and infection if the IUD is left in place. The removal of the IUD reduces these risks, although the procedure itself entails a small risk of miscarriage.

If she does not want to continue the pregnancy, and if therapeutic termination of pregnancy is legally available, inform her accordingly.

If she wishes to continue the pregnancy, make clear to her the increased risks of miscarriage, pre-term delivery and infection. Advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

The IUD strings are visible or can be retrieved safely from the cervical canal

Advise her that it is best to remove the IUD.

If the IUD is to be removed, remove it by pulling on the strings gently.

Explain that she should return promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

If she chooses to keep the IUD, advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

The IUD strings are not visible and cannot be safely retrieved

Where ultrasound is available, it may be useful in determining the location of the IUD. If the IUD is not located, this may suggest that an expulsion of the IUD has occurred.

If ultrasound is not possible or if the IUD is determined by ultrasound to be inside the uterus, make clear the risks and advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

Comments

The expert working group concluded that removing the IUD improves pregnancy outcome if the IUD strings are visible or can be retrieved safely from the cervical canal, and that the risk of miscarriage, pre-term delivery and infection is substantial if the IUD is left in place. The expert working group did not address the effects of hormonal IUDs during pregnancy, but there may be added risks to the fetus due to the hormonal exposure.

Systematic review question

What are the risks of adverse events if the IUD is removed or kept in place?
Level of evidence: II-3; indirect.

References from systematic review

1. Tatum HJ, Schmidt FH, Jain AK. Management and outcome of pregnancies associated with the Copper T intrauterine contraceptive device. American Journal of Obstetrics and Gynecology 1976;126:869-79.

2. Koetsawang S, Rachawat D, Piya-Anant M. Outcome of pregnancy in the presence of intrauterine device. Acta Obstetrica & Gynecologica Scandinavica 1977;56:479-82.

3. Skjeldestad FE, Hammervold R, Peterson DR. Outcomes of pregnancy with an IUD in situ—a population based case-control study. Advances in Contraception 1988;4:265-70.

4. Dreishpoon IH. Complications of pregnancy with an intrauterine contraceptive device in situ. American Journal of Obstetrics and Gynecology 1975;121:412-3.

Key unresolved issues

What are the pregnancy outcomes for women who become pregnant with an IUD in place and how do these outcomes differ between women who do and do not have the IUD removed ?

18

Should prophylactic antibiotics be provided for copper-bearing IUD insertion?

18. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?

Routine IUD insertion

Prophylactic antibiotics are generally not recommended for IUD insertion. However, in settings of both high prevalence of STIs and limited STI screening, such prophylaxis may be considered.

Counsel the IUD user to watch for symptoms of PID, especially during the first month.

Comments

The expert working group determined that prophylactic antibiotics for IUD insertion provide little, if any, benefit for women at low risk for STI.

Systematic review question

Does administration of prophylactic antibiotics decrease risk of infection during IUD insertion?
Level of evidence: I; direct

References from systematic review

1. Grimes DA, Schulz KF. Prophylactic antibiotics for intrauterine device insertion: a metaanalysis of the randomized controlled trials. Contraception 1999;60:57-63.

Key unresolved issues

Are prophylactic antibiotics for IUD insertion of any benefit in preventing PID in high STI prevalence settings?

19

What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?

19. What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?

Note: The Standard Days Method (SDM) is a fertility-awareness based method in which users must avoid unprotected intercourse on days 8–19 of the menstrual cycle.

SDM users who have 2 or more cycles outside the 26–32 day range, within any one year of use

Advise her that the method may not be appropriate for her because of a higher risk of pregnancy. Help her consider another method.

Initial provision of SDM for women whose menstual cycles are within the 26–32 day range

Provide another method of contraception for protection on days 8–19 if she desires. Give supplies in advance.

SDM users who have unprotected intercourse between days 8–19

Consider the use of emergency contraception if appropriate.

Comments

The expert working group concluded that the probability of pregnancy is increased when the menstrual cycle is outside the 26–32 day range, even if unprotected intercourse is avoided between days 8–19.

Systematic review question

What is the effectiveness of the Standard Days Method for women with cycles shorter or longer than 26–32 days? Level of evidence: II-3, direct

References from systematic review

1. Arevalo M, Sinau I, Jennings V. A fixed formula to define the fertile window of the menstrual cycle as the basis of a simple method of natural family planning. Contraception 2000;60:357-60.

Other key references

1. Wilcox AJ, Dunson D, Baird DD. The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study. British Medical Journal 2000;321:1259-62.

2. Wilcox AJ, Dunson DB, Weinberg CR, Trussell J, Baird DD. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. Contraception 2001;63:211-5.

Key unresolved issues

What are the most effective counselling and other communication strategies for maximizing consistent, correct and continued use of fertility awareness-based methods?

20

What examinations or tests should be done routinely before providing a method of contraception?

20. What examinations or tests should be done routinely before providing a method of contraception?

The examinations or tests noted apply to persons who are presumed to be healthy.

Those with known medical problems or other special conditions may need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. The WHO document, Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use, 2nd edition, 2000, may be useful in such circumstances.

The following classification was considered useful in differentiating the applicability of the various examinations or tests:

> Class A = essential and mandatory in all circumstances for safe and effective use of the contraceptive method.
>
> Class B = contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context. The risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.
>
> Class C = does not contribute substantially to safe and effective use of the contraceptive method.

These classifications focus on the relationship of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use may be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions.

Notes to the table:

* A WHO consultation held in Geneva, 9–10 October 2001, concluded that women at high risk of HIV infection should not use products that contain nonoxynol-9. Such women should avoid spermicides containing nonoxynol-9 and nonoxynol-9 lubricated condoms. Condoms without nonoxynol-9 lubrication are effective and widely available. Women at high risk of HIV infection should also avoid using diaphragms and cervical caps to which nonoxynol-9 is added. The contraceptive effectiveness of diaphragms and cervical caps without nonoxynol-9 has been insufficiently studied and should be assumed to be less than that of diaphragms and cervical caps with nonoxynol-9.

** It is desirable to have blood pressure measurements taken before initiation of COCs, CICs, POPs, POIs, and implants. However, in some settings, blood pressure measurements are unavailable. In many of these settings, pregnancy morbidity and mortality risks are high, and hormonal methods are among the few methods widely available. In such settings, women should not be denied use of hormonal methods simply because their blood pressure cannot be measured.

*** For procedures performed using local anaesthesia.

Specific situation	Combined oral contraceptives	Combined injectable contraceptives	Progestogen-only pills	Progestogen-only injectables	Implants	IUDs	Condoms	Diaphragm/ Cervical cap	Spermicides	Female sterilization	Vasectomy
Breast examination by provider	C	C	C	C	C	C	C	C	C	C	N/A
Pelvic/ genital examination	C	C	C	C	C	A	C	A	C	A	A
Cervical cancer screening	C	C	C	C	C	C	C	C	C	C	N/A
Routine laboratory tests	C	C	C	C	C	C	C	C	C	C	C
Haemoglobin test	C	C	C	C	C	B	C	C	C	B	C
STI risk assessment: medical history and physical examination	C	C	C	C	C	A	C*	C*	C*	C	C
STI/HIV screening: laboratory tests	C	C	C	C	C	B	C*	C*	C*	C	C
Blood pressure screening	**	**	**	**	**	C	C	C	C	A	C***

21

How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?

21. How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?

Initial and return visits

Provide up to one year's supply of pills, depending upon the woman's desires and anticipated use.

Programmes must balance the desirability of giving women maximum access to pills with concerns regarding contraceptive supply and logistics.

The re-supply system should be flexible, so that the woman can obtain pills easily in the amount and at the time she requires them.

Comments

The expert working group concluded that restricting the number of cycles of pills can result in unwanted discontinuation of the method and increased risk of pregnancy.

Key unresolved issues

What are the effects of providing different numbers of pill packs at initial and return visits on the consistent and continued use of COCs and POPs?

22

What follow-up is appropriate for COC, POP, implant and IUD users?

22. What follow-up is appropriate for COC, POP, implant and IUD users?

These recommendations address the minimum frequency of follow-up recommended for safe and effective use of the method. The recommendations refer to general situations and may vary for different users and different contexts. For example, women with specific medical conditions may need more frequent follow-up visits.

These methods do not protect against STI/HIV. If there is a risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.

COCs

An annual follow-up visit is recommended.

There are added benefits to a 3-month follow-up contact after initiation.

Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.

POPs (not breastfeeding)

No annual follow-up visit is required, but a follow-up contact after initiation is recommended at about 3 months.

Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.

POPs (breastfeeding)

No routine follow-up visit is required.

Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.

Advise the woman that when she either ceases or significantly reduces frequency of breastfeeding, she should return for further contraceptive advice and counselling.

Implants

No routine follow-up visit is required.

Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.

Advise the woman to return when it is time to have the implants removed.

IUDs

A follow-up visit is recommended after the first menses or 3–6 weeks following insertion.

Advise the woman to return at any time to discuss side-effects or other problems, or if she wants to change the method.

For devices that have a high rate of expulsion, more frequent follow-up than above may be indicated.

Advise her to return when it is time to have the IUD removed.

Comments

The expert working group concluded that follow-up visits or contacts should include, at a minimum, counselling to address issues such as side-effects or other problems, correct and consistent use of the method, and protection against STIs. Additional assessment may be appropriate, e.g., pelvic examination to check for IUD displacement.

Key unresolved issues

Does having a 3-month follow-up visit or contact (versus no scheduled early return) after initiating COC and POP use increase consistent, correct and continued use?

23

How can a provider be reasonably sure that a woman is not pregnant?

23. How can a provider be reasonably sure that a woman is not pregnant ?

The diagnosis of pregnancy is important. The ability to make this diagnosis early in pregnancy will vary depending on resources and settings. Highly reliable biochemical pregnancy tests are often extremely useful, but not available in many areas. Pelvic examination, where feasible, is reliable at approximately 8–10 weeks since the first day of the last menstrual period.

The provider can be reasonably certain that the woman is not pregnant if she has no symptoms or signs of pregnancy and meets any of the following criteria:

- has not had intercourse since last normal menses
- has been correctly and consistently using a reliable method of contraception
- is within the first 7 days after normal menses
- is within 4 weeks postpartum for non-lactating women
- is within the first 7 days post-abortion or miscarriage
- is fully or nearly fully breastfeeding, amenorrhoeic, and less then 6 months postpartum.

Technical meeting to develop consensus on evidence-based guidelines for family planning and to review the decision-making tool of the essential care practice guide

London, 3-6 October 2001

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